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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,840	10/30/2003	David W. Wynn	MCP-5021	9284

27777 7590 05/28/2008  
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EXAMINER
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GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

MAIL DATE	DELIVERY MODE
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05/28/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/697,840	<b>Applicant(s)</b> WYNN ET AL.	
	<b>Examiner</b> KONATA M. GEORGE	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-6,9-15,17-21 and 24-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,9-15,17-21 and 24-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1, 3-6, 9-15, 17-21 and 24-30 are pending in this application.

### ***Action Summary***

Any rejections of record that are not repeated below are considered withdrawn.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 3-6, 9-15, 17-21 and 24-30 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-6, 9-15, 17-21 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratnaraj et al. (US 5,658,919) in view of Singh et al. (US 5,759,579) Robinson et al. (US 2003/0049316) and Mukherji et al. (US 6,565,877)

Applicants claim a liquid suspension of particles of NSAID and/or acetaminophen wherein the particles are covered with one layer of a controlled release composition wherein the composition comprises as insoluble film former polymer and an enteric polymer and wherein the suspension comprises a vehicle comprising water.

***Determination of the scope and content of the prior art***  
**(MPEP §2141.01)**

Ratnaraj et al. teach a novel suspension system containing acetaminophen (col. 2, lines 46-55). Column 4, lines 1-2 teach the system is suitable from suspending acetaminophen powder. The suspending system (examiner relates it to the vehicle as claimed by applicant) comprises xanthan gum and a mixture of microcrystalline cellulose and sodium carboxymethylcellulose (col. 2, lines 51-53). Table 1 of columns 6 and 7 disclose the addition of water to the vehicle, a glycol such as propylene glycol, sweeteners and flavoring agents.

***Ascertainment of the difference between the prior art and the claims***  
**(MPEP §2141.02)**

Ratnaraj et al. do not teach the particles being coated with a controlled release composition, the composition having a therapeutic effect of least about 8 hours and the

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NSAID is a propionic acid derivative or the ratios of the polymers. It is for this that Singh et al., Robinson et al. and Mukherji et al. are joined.

Singh et al. teach a pharmaceutical suspension system comprising finely divided pharmaceutically active compounds and liquid excipient suspension system comprising water, and the suspending agents' xanthan gum and hydroxypropyl methylcellulose (col. 1, lines 4-12). Column 2, lines 30-35 teach that the active compounds can be non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesic drugs such as acetaminophen. Of the NSAIDs for use in the system propionic acid derivatives can be employed (col. 3, lines 3-7). Preservatives, sweeteners, and flavoring agents can be used in the system (col. 4, lines 5-10). The various examples in columns 4-7 teach the concentrations of the drug as about 3.20% and a least 40% water.

Robinson et al. teach tablets comprising NSAID and/or acetaminophen and wherein the particles are coated with a taste masking composition. The taste masking composition can comprise an insoluble film-forming polymer (cellulose acetate or ethyl cellulose) and an enteric polymer (EUDRAGIT™ E-100) (paragraph 0021).

Mukherji et al. teach a taste masked composition comprising an active agent and a coating comprising two enteric polymers. Column 2, lines 48-61 teach examples of the enteric polymers that can be used in the coating of bitter tasting drugs having a ratio of 1:9 to 9:1.

***Finding of prima facie obviousness***  
***Rational and Motivation (MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Ratnaraj et al. (a suspension of acetaminophen) in view of Singh et al. (a suspension of NSAIDs) with Robinson et al. and Mukherji et al. to arrive at the claimed invention. It is known that acetaminophen and NSAIDs are drugs that do not possess a pleasant taste; therefore coating these drugs to mask the taste is obvious and well known throughout the art. Therefore, one of ordinary skill would look to the coating compositions of Robinson et al. and Mukherji et al. to coat the drugs of Ratnaraj et al. or Singh et al. for the purpose of masking the taste of the drugs. It is the position of the examiner that since the polymers used in taste masking the drug are the same as those claimed for controlling the release of the composition, the release profile (i.e. the duration of therapeutic effect, etc. as claimed by applicant) for the composition would also be met.

With respect to the ratio of the polymers in the controlled release layer, one of ordinary skill in the art could look to paragraph 0021 of Robinson et al. for guidance in determining the appropriate ratio of the polymers to achieve the optimum results of the coating.

***Conclusion***

Claims 1, 3-6, 9-15, 17-21 and 24-30 are rejected.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Konata M. George/  
Examiner, Art Unit 1616